In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 17-564V
Filed: October 9, 2019
PUBLISHED

SUZANNE DEMITOR,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Finding of Fact; Shoulder Injury Related to Vaccine Administration; SIRVA; Tetanus Diphtheria acellular Pertussis (Tdap) Vaccine; Onset

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Kimberly Shubert Davey, U.S. Department of Justice, Washington, DC, for respondent.

FINDING OF FACT[1]

On April 25, 2017, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012), alleging that as a result of her July 8, 2014 tetanus-diphtheria-acellular pertussis ("Tdap") vaccination she suffered a Shoulder Injury Related to Vaccine Administration or "SIRVA," which is an injury listed on the Vaccine Injury Table. 42. U.S.C. §300aa-14(a) as amended by 42 CFR § 100.3. Respondent recommended that compensation be denied, arguing, *inter alia*, that there is not preponderant evidence that petitioner's shoulder pain began within the 48-hour period required by the Vaccine Injury Table and that petitioner's medical history does not conform to the criteria for establishing a SIRVA. For the reasons described below, I now issue the below finding of fact. I conclude that petitioner has not established by preponderant evidence that the onset of her shoulder pain was within 48 hours of her vaccination or that her pain was limited to the shoulder in which she received her vaccination, both of which are requirements for establishing the presence of a Table SIRVA.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

I. Procedural History

As noted above, petitioner initiated this action on April 25, 2017, alleging a Table Injury of SIRVA. (ECF No. 1.) Pursuant to the Vaccine Injury Table and accompanying Qualifications and Aids to Interpretation ("QAI") an injury must satisfy the following four criteria to be considered a SIRVA:

> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; and
>
> (ii) Pain occurs within the specified time-frame; and
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. §100.3(c)(10).

Based on the allegations in the petition, the case was assigned to the Special Processing Unit ("SPU"). (ECF No. 6.) The SPU "is designed to expedite the processing of claims that have historically been resolved without extensive litigation." (*Id*. at 1.)

Petitioner initially supported her claim with the filing of medical records marked as Exhibits 1-4 and she filed a Statement of Completion on April 27, 2017. (ECF Nos.7-8.) However, following the initial status conference, additional medical records marked as Exhibits 5 and 8 were later filed along with an affidavit by petitioner marked as Exhibit 6 and an affidavit by her husband marked as Exhibit 7. (ECF Nos. 10-11.) Petitioner filed a second Statement of Completion on June 27, 2017. (ECF No. 13.)

On October 17, 2017, respondent confirmed that he had completed a review of this case and indicated his intention to litigate. (ECF No. 16.) He later filed his Rule 4(c) Report on December 11, 2017. (ECF No. 17.)

In his report, respondent raised a number of points based on his review of the medical records. Specifically, he contended that petitioner does not meet the criteria for a Table SIRVA because: (1) she had a history of "deep, aching bilateral mid-to-upper thoracic and cervical pain that was aggravated with overhead movements, reaching out, and repetitive use of the arms;" (2) "it is unclear whether petitioner's pain occurred within 48 hours of vaccine administration;" (3) "when petitioner first presented for

treatment after vaccination, she complained of left arm, neck and shoulder pain;" and (4) "petitioner had presented to a chiropractor on multiple occasions from 2011 through 2013 for segmental cervical dysfunction with muscle spasm and symptoms exacerbated with shoulder and arm movement."[2] (*Id.* at 7-8.)

The case was subsequently removed from the SPU and reassigned at random to Special Master Millman on December 22, 2017. (ECF Nos. 19-20.) On January 31, 2018, Special Master Millman held a status conference with the parties. (ECF No. 22.) Due to her anticipated retirement, she advised that "this case needs a factual hearing which will not be scheduled until it is reassigned to another special master." (ECF No. 22.) No further action was taken in this case until it was reassigned to me on June 4, 2019. (ECF Nos. 24-25.)

On June 6, 2019, I issued a Scheduling Order informing the parties that I intended to hold a video fact hearing in this case during the week of July 15, 2019. (ECF No. 26.) Once the parties selected a hearing date, the parties were advised that the prehearing evidentiary record would close on July 8, 2019. (ECF No. 28.) No further evidence was filed.

The video fact hearing was held on July 16, 2019. Petitioner and her husband testified. (*See* ECF No. 36, Transcript of Proceedings ("Tr"), July 16, 2019).

Subsequently, petitioner was ordered to file additional records that were identified during the hearing. (ECF No. 33.) These records were filed on September 5, 2019 as Exhibits 10-14. (ECF No. 37.)

Accordingly, this case is now ripe for a finding of fact.

II. Factual History

a. As Reflected in the Medical Records

1. Pre-Vaccination Condition

In the three-year period immediately preceding her alleged injury-causing Tdap vaccination, petitioner saw her primary care provider only twice. On April 29, 2011, she presented with a chief complaint of heart palpitations. (Ex. 2, pp. 1-3.) At that time her

[2] Although petitioner did not specifically plead an alternate cause-in-fact claim, respondent contended that petitioner would fail the *Althen* test for similar reasons. (*See* ECF No. 17, pp. 8-9 (citing *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (holding that to successfully demonstrate causation-in-fact, petitioner bears a burden to show: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury).)

medical history was noted to include allergic rhinitis (improved) and pyelonephritis[3] in 2008, as well as prior surgeries including appendectomy, cesarean section, and tubal ligation. (*Id*. at 1-2.) No musculoskeletal complaints were noted and musculoskeletal exam notations were limited to "no deformity or scoliosis noted of thoracic or lumbar spine." (*Id*. at 1.)

On May 23, 2011, petitioner returned to her primary care doctor for an annual exam. (Ex. 2, pp. 3-12.) She was reportedly feeling well and had no complaints at this visit. (*Id*. at 6-7.) Her musculoskeletal exam noted as follows: "Denies muscle cramps, joint pain, joint swelling, presence of joint fluid, back pain, stiffness, muscle weakness, arthritis, gout, loss of strength, muscle aches, chronic neck pain, and chronic back pain." (*Id*. at 5.)

No further primary care records from this period have been filed in this case. However, petitioner subsequently began visiting a chiropractor on September 23, 2011.[4] (Ex. 4, p. 1.) At that time, petitioner had a chief complaint of "lumbosacral junction and left sacroiliac joint region(s) – aching pain." (*Id*.) She had an additional complaint of "bilateral (but more intense on the left) upper thoracic and cervical region – aching pain and spasm." (*Id*.) Petitioner indicated that the problem began on September 16, 2011, and that she "attributes the problem to exercising." (*Id*.) Petitioner's chiropractor diagnosed muscle spasms and segmental dysfunction of the sacral region as well as the lumbar, thoracic, and cervical levels. (*Id*.)

On May 9, 2012, petitioner returned to her chiropractor with essentially the same complaints. (Ex. 4, p. 3.) She noted that her lumbosacral and sacroiliac pain had been aggravated approximately a week earlier with no identified reason. (*Id*.) With regard to her bilateral mid thoracic to cervical pain, she rated her pain intensity as a three on a one to ten scale but noted pain of six out of ten when aggravated. (*Id*.) She indicated that her condition was "aggravated with overhead movements of the arm, reaching out with the arm and repetitive use of arms." (*Id*.) However, the record notes that she "denies radiation of symptoms into the arms." (*Id*.) At this time, the pain was noted to be more intense on the right. (*Id*.)

At this time, petitioner's chiropractor tested her cervical range of motion. He recorded "active extension, right lateral bend and right rotation restricted 15% with tension locally 4/10." (Ex. 4, p. 3.) He also noted "cervical compression with lateral bending right – with moderate pressure – produce pain locally – produce tension locally 5/10." (*Id*. at 4.) To his previous assessment, the chiropractor added "neck sprain/strain" to his assessment along with sprain/strain of the thoracic, lumbar, and sacrum. (*Id*.)

[3] Pyelonephritis is inflammation of the kidney and renal pelvis due to bacterial infection. Dorland's Illustrated Medical Dictionary, 32nd Ed., p. 1559.

[4] The record of petitioner's September 23, 2011 chiropractic visit indicates that she had prior treatment with the same chiropractor that had "provided complete relief." The date of this prior treatment is not indicated; however, onset of the complaint for which she was being seen was listed as September 16, 2011. (Ex. 4, p. 1.)

Petitioner returned to the chiropractor again on August 17, 2012. (Ex. 4, pp. 6-8.) Petitioner's complaints and the chiropractor's findings and assessment were unchanged, but a progress note indicated "The condition has exacerbated, but unsure why?" (*Id*. at 7.) She returned again three days later on August 20, 2012. (*Id*. at 9-13.) Her record was again substantially the same, but this time noted that "[t]he patient reports feeling worse since the last visit but has been ill and not feeling well overall." (*Id*. at 9.) On March 20, 2013, petitioner was seen by the chiropractor again. No additional notation was added to her record. (Ex. 4, pp. 14-16.)

2. Alleged Injury-Causing Vaccination

On July 8, 2014, petitioner received a tetanus-diphtheria- acellular pertussis ("Tdap") vaccination in her left deltoid as the Walla Walla County Health Department in Walla Walla, Washington. (Ex. 1, p. 5; Ex. 5, p. 3.) She returned two days later and received a measles, mumps, and rubella ("MMR") vaccination in her right arm on July 10, 2014. (Ex. 1, p. 5; Ex. 5, p. 3.) Petitioner's screening questionnaire for her MMR vaccination indicates that she has not had a serious reaction to a vaccine in the past. (Ex. 5, p. 7.) However, petitioner denies that this is accurate. (Ex. 6, p. 3.) Petitioner did not seek any medical care for any reason for the remainder of calendar year 2014.

3. Post-Vaccination Condition and Treatment

On January 23, 2015, petitioner returned to her chiropractor approximately six months after her July 2014 vaccinations. (Ex. 4, pp. 17-18, 21-22.) At that time, petitioner filled out a patient intake form. She listed her current complaints as "[left] arm pain, neck, shoulder." (*Id*. at 21.) She listed the date of onset as "1 month" and for probable cause questioned "nerve?" (*Id*.) For "History of current complains" she marked "none." (*Id*.) Petitioner also marked "none" when prompted to list "all significant trauma." (*Id*.)

The chiropractor characterized petitioner's symptoms as "mid back through upper neck region left." (Ex. 4, p. 17.) He recorded the following on examination:

> Neck, upper mid back, left shoulder blade, and left upper posterior arm exhibits Asymmetry/Misalignment of moderate departure from center, or neutral, in relation to adjacent structures, palpatory Pain/Tenderness of moderate intensity, Range of Motion abnormality (hypomobile relative to patient) of moderate degree, and Tissue/Tone changes (hypertonic relative to patient) – left paracervical and left parathoracic, of moderate intensity.

(*Id*.) Petitioner was diagnosed as having "subluxation/nonallopathic lesion (segmental dysfunction)" of both the cervical and thoracic region as well as muscle spasm. (*Id*.)

The chiropractor opined that the subluxations[5] he observed during the examination "are capable of producing the complaints described" by petitioner. (*Id*.)

On January 26, 2015, petitioner returned to the chiropractor. She reported "some improvement in symptoms since last visit." (Ex. 4, p. 19.) Her subjective report indicated "mid back through upper neck region left: moderate, frequent, getting better since last visit, complaint grade 5 on a scale from 0 to 10." (*Id*.)

Petitioner returned again to the chiropractor on March 4, 2015. (Ex. 4, pp. 26-27.) At this visit, petitioner reported "a return of symptoms or increase of complaints since last visit. She stated: 'Lt. shoulder at subacromial area pain following vaccination on 7/8/14 persisting without relief from treatment." (*Id*. at 26.) However, the chiropractor still listed petitioner's symptoms as "mid back through upper neck region left: moderate-severe, constant, remains unchanged since last visit, complaint grade 7 on a scale from 0 to 10." (*Id*.) The chiropractor's assessment remained unchanged, but he noted that petitioner "is not responding to treatment as expected." (*Id*.)

Petitioner did not seek any further medical treatment until nine months later; however, a note within petitioner's medical record from the Walla Walla County Health Department dated November 9, 2015 indicates as follows:

> Client here today requesting and is given her immunization record. She also is requesting information regarding a stated reaction to her Tdap vaccine that she received on 7-8-14. She states that when she came in on 7-10-14 to receive her MMR vaccination that she had c/o red, hot and painful L arm after receiving her Tdap vaccine. She states that the nurse who saw her in clinic that day gave her ice packs and advised her to use Benadryl cream and continue with the cold packs and to take Tylenol or ibuprofen and to see her PCP or RTC if sx worse or did not improve, to which she further states that the "redness went away in about 1 wk["] and the initial pain took "about 2 wks to go away" and then it all resolved. She states that with exercise it got worse "then it seemed to get worse and it went in to my neck 1st and then in to my shoulder." "I lost my job 18 months ago and I have no insurance and no money of my own." I saw a chiropractor "probably about 3 x" since 7-10-14. "I don't know if the pain is triggered by too much exercise or housework. The pain radiates down my arm and every morning when I get dressed it hurts affecting my daily life." "I don't believe in vaccines. I only did this for immigration to save my husband $750.00. My children are not vaccinated." She is given the Tdap VIS information sheet and advised that this is generally a local reaction to the vaccine. She denies any axillary lymph node swelling at the time of vaccine. She states that she has been talking to a navigator at AHMG and she may see Dr. Hudson, an

[5] In medicine "subluxation" generally refers to an incomplete or partial dislocation; however, specific to the chiropractic context, subluxation refers to "any mechanical impediment to nerve function." Dorland's Illustrated Medical Dictionary, 32nd Ed., p. 1791.

> orthopaedic physician for a consult. She is referred to SOS clinic for evaluation. RTC prn JSRN

(Ex. 5, pp. 8-9.)[6]

About a month later, on December 3, 2015, petitioner sought orthopedic treatment for the first time on a self-referred basis with a chief complaint of left shoulder pain. (Ex. 3, pp. 1-5.) At this visit, petitioner associated her shoulder pain to her July 8, 2014 vaccination. She reported that "[t]hat evening, following the injection, she began to having [sic.] left arm swelling, redness and 'terrible pain.' The swelling and redness have decreased somewhat, though she continues to have these symptoms since the injection. Her pain is constant level 2-8/10." (*Id*. at 1.) Petitioner also indicated that quick movements aggravate her symptoms and that she "has complaints of radiating pain to her hand, instability stiffness and weakness." (*Id*.) The orthopedist also noted that "[s]he has had neck pain in the past, but not at this time." (*Id*.) Petitioner's symptoms were reportedly not improving and she noted two prior chiropractic visits "which were not helpful." (*Id*.) Under the heading "orthopedic problems," petitioner's condition is listed as "neck, shoulder and arm." (*Id.*)

Orthopedic examination revealed no swelling, ecchymosis,[7] muscle wasting, or masses. (Ex. 3, p. 3.) Petitioner exhibited "[diffuse tenderness about the shoulder, not well localized to any specific area." (*Id*.) Petitioner demonstrated left shoulder range of motion of 140 degrees forward flexion and 80 degrees abduction with mild to moderate pain at the extreme. She had internal rotation to T12 with mild to moderate pain at the extreme and external rotation of 45 degrees with only mild pain at the extreme. (*Id*.) She was positive for impingement signs, painful abduction arc and on cross arm adduction testing, but negative on supraspinatus testing. (*Id*.) X-ray imaging showed mild early degenerative changes of the acromioclavicular joint. (*Id*. at 4.)

In his assessment, the orthopedist characterized petitioner's condition as "a chronic shoulder ache and nonacute flare." (*Id*.) The orthopedist's assessment indicated "left shoulder pain," "biceps tendinitis on left," and "subacromial tendinitis of left shoulder." (*Id*.) He recommended an MRI but noted petitioner's lack of medical insurance at that time. (*Id*.) He also noted that "[a]t this point in time she is wishing me

[6] Petitioner disputes the accuracy of this account. (Ex. 6, p. 3.) In her affidavit, she states that "the narrative is incomplete and incorrect;" however, she did not specify in what ways the account was inaccurate. (*Id*.) She noted that the facility would not change the record of her July 10, 2014 visit and that the nurse she spoke to had not been present at the time of her MMR vaccination. (*Id*.) In her hearing testimony, petitioner reiterated these concerns. (Tr. 52-53, 105-06.) She agreed that she reported her redness to have resolved but disputed that she stated that all of her symptoms had resolved. She also disputed that she had attributed the condition to exercising, indicating instead that she had meant to indicate that exercising exacerbated her symptoms. (*Id.*) She testified that she could not recall what prompted her to seek out her vaccination record at that time. (Tr. 104-05.)

[7] "Ecchymosis" refers to "a small hemorrhagic spot, larger than a petechia, in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch." Dorland's Illustrated Medical Dictionary, 32nd Ed., p. 588.

to document her current symptoms and she is going to pursue insurance coverage. She feels her current symptoms are due to a condition called 'SIRVA' or 'shoulder injury related to vaccine administration.' I unfortunately have not heard that before and would have a difficult time speaking to that etiology." (*Id*.)

Subsequently, on December 21, 2015, petitioner returned to her chiropractor. (Ex. 4, pp. 28-29.) Petitioner reportedly had a chiropractic adjustment, though the chiropractor noted that petitioner associates her condition to her vaccination and recommended orthopedic treatment. He characterized petitioner's injury as "outside realm of chiropractic."[8] (*Id*. at 28.)

On June 22, 2016, petitioner briefly resumed treatment with her chiropractor and completed a new intake form. (Ex. 11, p. 27.) In this form, petitioner reported that her arm and shoulder pain began on July 8, 2014, as a result of a Tdap vaccine received that day. (*Id*.) She noted December of 2014 to mark a turning point for the worse and described some of her prior treatment. (*Id*.) Petitioner returned on June 24, 2016. (*Id*. at 32-33.)

Petitioner returned to chiropractic care, again in early 2019. (Ex. 11, p. 14.) On January 4, 2019, she completed an additional updated intake form. (*Id*. at 16.) In this form, she indicated that her left shoulder pain began on July 8, 2014, and that the cause was her Tdap vaccine.[9] (*Id*.) She returned several times in January, February and July of 2019. (*Id*. at 1-17.)

Additional records were filed regarding a wrist fracture occurring in late 2017 and an ankle injury in early 2019, but no mention is made of petitioner's shoulder condition. (Exs. 12-14.[10])

b. As Reflected in Testimony

Petitioner denied that she had any prior injury or mobility issue in relation to her left arm or shoulder prior to receiving her July 8, 2014 Tdap vaccination. (Ex. 6, p. 1; Tr. 7-9.) She indicated that hours after receiving the vaccination, she experienced redness, swelling, throbbing, and pain in her shoulder and further indicated that the pain was "ever present" since the date of her vaccination. (Ex. 6, pp. 1-2; Tr. 46.)

Petitioner indicated that she had never experienced this type of pain before and testified that she knew immediately that the vaccine caused her injury. (Ex. 6, pp. 1-2; Tr. 47.) She confirmed that the redness and swelling resolved over a couple weeks, but indicated that the pain persisted. (Tr. 17.) She testified that during the time from her

[8] This record includes a description of positive findings on examination related to neck, upper mid back, and left shoulder; however, these findings are repeated verbatim from prior visits. (Ex. 4, pp. 28-29.)

[9] Petitioner again associated no trauma with her injury. (Ex. 11, p. 16.)

[10] Exhibit 13 does include some records dated July 8, 2014; however, no encounter is indicated, and the admission diagnosis is noted as being for administrative purposes. (Ex. 13, pp. 1-6.)

vaccination until she first sought medical care from her chiropractor, she experienced what she called "dramatic" changes to her routine and indicated that she was "doing everything in my life to avoid feeling the pain escalate." (Tr. 19-20.)

Petitioner further reports that on July 10, 2014, she informed a nurse at the Walla Walla Health Department about the redness and swelling she experienced in her left arm when she returned there to receive her MMR vaccination. (Ex. 6, p. 2; Tr. 13-15.) She reports that she was told to use an icepack and take Benadryl and that the pain would go away in a few days. (*Id*.) She indicated that she treated with Advil and Benadryl, which provided only temporary relief, but further stated that "I had no medical insurance and felt I could not afford seeing a doctor for treatment, so I tolerated the pain the best I could. I also hoped the nurse at the Walla Walla Health Department was correct and the symptoms would go away with time." (Ex. 6, p. 2.)

Petitioner averred that "[w]ithin a week or two, I couldn't sleep at night and could not lift my arm up, to the side, or reach back hardly at all. The initial symptoms of redness, swelling, and throbbing pain did become less severe, but I continued to feel numbness, aching and tingling in my arm. I stopped exercising because of this condition." (Ex. 6, p. 2.) She also testified that she took a road-trip to visit a friend in Seattle about a week after her vaccination. (Tr. 16-17.) She recalled that her friend was concerned about her driving in light of her arm pain. (*Id*.)

Petitioner indicated, however, that "[i]n December, 2014, my husband and I flew to New York to visit relatives. Whether because of the bitter cold in New York or the flight or some other reason, the pain in my left arm greatly increase[d]. The pain radiated down the entire length of my arm." (Ex. 6, p. 2.) Petitioner testified that her trip to New York marked a distinct escalation in the intensity of her pain. She testified that during the trip she had to change her sleeping habits and was almost crying due to the pain. (Tr. 21-22.)

Thereafter, due to her inability to afford a physician, petitioner indicated that she began treatment with a chiropractor. (Ex. 6, p. 2.) She testified that the chiropractic visit was a response to the pain she experienced while traveling to New York. (Tr. 22.) She indicated that initially the chiropractic treatment reduced, but did not eliminate, her pain, but that her pain worsened after her third visit. (Ex. 6, p. 2; Tr. 26.) Petitioner indicated that she has a persistent "dull ache" in her left arm which is aggravated by certain activities. (Ex. 6, p. 2; Tr. 19, 24-25, 34-38.)

At some point during her course of chiropractic treatment, the chiropractor suggested that he felt something fluid-like in the area of petitioner's bursa. (Tr. 26-27, 120.) Petitioner indicated that initially she did not want to discuss with her chiropractor her belief that her injury was vaccine-related, but later decided to discuss what she believed caused her injury. (*Id*. at 28-29.) During this period, petitioner also came to

believe her condition would not improve and in early 2015 discovered the concept of SIRVA by Google search.[11] (*Id*. at 40, 63.)

Petitioner's chiropractor recommended that she seek out an orthopedist. (Tr. 120.) However, after one visit, petitioner was unable to return because his office closed. (Tr. 43.)

Petitioner's husband, Timothy Demitor, also provided testimony. (Ex. 7; Tr. 127-172.) He indicated that petitioner was generally in good health and did not previously have problems with her left shoulder, but that "within hours" of receiving her Tdap vaccination, she showed him how her left arm was swollen and red and complained that her arm hurt. (Ex. 7, p. 1; Tr. 128-29, 153-54.) Mr. Demitor also indicated that he was present at the time of petitioner's July 10, 2014 MMR vaccination and that he witnessed petitioner report her redness and swelling to the nurse. (Ex. 7, pp. 1-2; Tr. 131-33.)

Mr. Demitor indicated that petitioner is not typically the type to complain, but he noticed that in the months after her vaccination she needed his help with lifting and vacuuming and that she was having trouble with her sleeping position. (Tr. 135-36.) He also recalled that petitioner complained a lot about her shoulder pain during their trip to New York in December of 2014. (*Id*. at 137.)

Mr. Demitor also "vaguely" recalled being present for a later conversation in about November of 2015 with the supervising nurse at Walla Walla County Health regarding whether petitioner's vaccine record was complete. (Tr. 161-63.) However, he could not recall the details of that discussion beyond discussing the lack of a notation in the records regarding the recommendation to take Benadryl and anti-inflammatories. (*Id*.) He did recall, however, that around the time they discovered that Walla Walla County Health had not recorded the vaccine-reaction she reported on July 10, 2014, he was able to discuss the issue with the nurse who administered the vaccine. (*Id*. at 139-142, 159-60.) He testified, however, that she would not volunteer any information and that, while she remembered that they came in for vaccinations, would not confirm that she remembered any details. (*Id*.) He indicated that when asked if she remembered, she would only say "well, that was a really long time ago." (*Id*. at 141-42.)

III. Legal Standard Applied

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a "preponderance of the evidence." 42 U.S.C. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than its nonexistence." *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. 42 U.S.C. § 300aa-11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific

[11] Petitioner testified that she was provided a vaccine information sheet at the time of her Tdap vaccination, but that she did not read it at the time. (Tr. 62.)

evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." 42 U.S.C. § 300aa-13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (*i.e*., presenting all relevant information on a patient's health problems). *Cucuras v. Sec'y of Health & Human Servs.,* 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Doe v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"); *Rickett v. Sec'y of Health & Human Servs.*, 468 Fed. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), aff'd, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974, 113 S. Ct. 463, 121 L.Ed.2d 371 (1992) (*citing United States v. United States Gypsum Co.*, 333 U.S. 364, 396, 68 S. Ct. 525, 92 L.Ed. 746 (1948) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (*quoting Murphy*, 23 Cl. Ct. at 733). Ultimately, a determination regarding a witness's credibility is often needed when determining the weight that such testimony should be afforded. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

IV. Findings of Fact

a. Onset of Petitioner's Shoulder Pain

In light of the above-discussed legal standard and based upon my review of the entire record, I do not find preponderant evidence that petitioner's alleged vaccine-caused shoulder pain began within 48 hours of her July 8, 2014 Tdap vaccination. Rather, I find that the chronic shoulder pain constituting petitioner's alleged SIRVA, more likely than not, began in late December of 2014, more than five months following the date of her July 8, 2014 Tdap vaccination. Petitioner's first treatment record relative to her alleged vaccine injury is her chiropractic visit of January 23, 2015. At that time, she reported that the onset of her condition was one month prior, which would place the onset of her condition in late December of 2014. (Ex. 4, pp. 17-18, 21.)

Petitioner's January 23, 2015 chiropractic record is in itself particularly persuasive for a number of reasons. First, as noted above, it is petitioner's first

treatment record for her shoulder pain. Thus, it is the most contemporary to her injury and reflects the freshest available recollection of the onset of her condition. Further, as her first treatment record, it likely reflects petitioner's inherent interest in seeking treatment appropriate to her actual injury, suggesting that she would have an incentive to be as accurate as possible in reporting her history. As the Federal Circuit has noted, the weight afforded to contemporaneous records is due to the fact that they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium." *Cucuras*, 993 F.2d at 1528.

Also significant, the history reflected in the record of petitioner's January 23, 2015 chiropractic visit derives from her own handwritten intake form. Thus, it cannot be said to reflect any transcription mistake or miscommunication on the part of the chiropractor or his office. Nor can petitioner reasonably suggest that she was incompletely or incorrectly paraphrased. Rather, the report of a "1 month" onset is her own report verbatim. Moreover, petitioner did not disclaim this record in her testimony. She testified on direct examination that she was "not sure" what her thought process was when filing out the January 23, 2015 chiropractic intake form and couldn't remember why she attributed her pain to a possible nerve injury.[12] (Tr. 23-24.)

Finally, petitioner's initial report that the onset of her condition occurred in December of 2014 – one month prior to her January 23, 2015 chiropractic visit – is consistent both with her overall pattern of chiropractic treatment over several years and with her recollection as stated in both her affidavit and hearing testimony that she experienced a distinct onset of significant pain when she flew to New York at about that time. (Ex. 6, p. 2; Tr 21-22.) Although petitioner expressed this as an increase or exacerbation of her pain, in the context of her prior history of cervical pain (Ex. 4, p. 16) as well as her subsequent characterization of her condition as "arm pain, neck and shoulder" (Ex. 4, p. 21; Tr. 23), this remains *potentially* consistent with an aggravation of prior complaints of pain unrelated to vaccination for which she previously sought chiropractic care.[13] Moreover, petitioner confirmed in her testimony that the pain she

[12] Later, on cross examination, petitioner suggested that at the time she completed the form she suspected her Tdap injection may have hit a nerve. (Tr. 95.) Petitioner also suggested, based on her handwriting, that she was rushed when completing the form. (Tr. 95-96.) However, when subsequently asked regarding the same form why she reported an ongoing exercise routine despite testifying that the injury had inhibited her exercise, petitioner again indicated that she is "not sure what I was thinking when I wrote that down." (Tr. 97.)

[13] Petitioner's prior chiropractic history includes prior instances where she did not delay in seeking treatment for what she reported as exacerbation of pain occurring for unknown reasons. (Ex. 4, p. 7.) Although petitioner's prior chiropractic records do not directly implicate her shoulder, it is noted that her cervical condition was "aggravated with overhead movements, reaching out, and repetitive use of the arms." (Ex. 4, p. 3.) Also of note, although petitioner had last seen her chiropractor in March of 2013, her records report no resolution of her cervical complaints. (Ex. 4, pp. 14-16.) Additionally, petitioner testified that her chiropractic treatments beginning in January 2015 did provide temporary relief of her symptoms and were therapeutic. (Tr. 26, 99.) Notably, petitioner later completed an updated chiropractic intake form that indicated that December 2014 marked "a turn for the worse" in her condition. (Ex. 11, p. 27.) However, this form was completed in June of 2016 and is far less contemporaneous to the relevant events than the January 2015 intake form.

experienced during her New York trip was in fact the impetus for her January 23, 2015 chiropractic visit. (Tr. 22.)

Although petitioner has contended that she reported an immediate vaccine reaction to the Walla Walla County Health Department on July 10, 2014, that contention remains unsupported by her medical records as the facility did not initially record that report and later declined to amend its record. (Ex. 5, p. 7-9; Ex. 6, p. 3.) Mr. Demitor's testimony additionally confirmed that the nurse who reportedly was told of petitioner's initial vaccine reaction could not recall or would not confirm that conversation. (Tr. 141-42.)

To the extent her report was later memorialized upon her subsequent return to the county health department in November of 2015, that narrative reflects a recollection far less contemporaneous to the onset of her condition, occurring more than ten months after she first sought treatment and nearly a year and a half after her Tdap vaccination. *See, e.g. Vergara v. Sec'y of Health & Human Servs.*, 08-882V, 2014 WL 2795491, *4 (Fed. Cl. Spec. Mstr May 15, 2014) ("Special Masters frequently accord more weight to contemporaneously-recorded medical symptoms than those recorded in later medical histories, affidavits, or trial testimony."). Moreover, even if credited, the record of petitioner's November 2015 return to the Walla Walla County Health Department documents only a mild, transient vaccine reaction rather than the onset of chronic shoulder pain.

Petitioner has stressed that at the time of the alleged July 10, 2014 report of symptoms, she was experiencing pain, redness and swelling. (Ex. 5, pp. 8-9; Ex. 6, p. 2.) Though petitioner disputes the accuracy of the record, she is reported in that account to have told the Walla Walla County Health Department as of November 2015 that her initial pain, redness and swelling resolved within one to two weeks of vaccination. (Ex. 5, pp. 8-9; Tr. 51-52.) Although she later reported to her orthopedist that the symptoms were ongoing and that the swelling and redness had only "decreased somewhat," the orthopedist failed to detect any swelling upon examination at that time. (Ex. 3, pp. 1, 3.) Petitioner has acknowledged in testimony that, at a minimum, she agrees that the redness and swelling resolved within a couple weeks of vaccination. (Tr. 17, 52.) Moreover, she testified that the nurse's impression at that time was that she was experiencing only a temporary reaction. (Tr. 13-15, 73.)

I have considered petitioner's testimony that her condition began immediately after her July 8, 2014 Tdap vaccination, including her recollection of being in pain during a road trip occurring about a week after her vaccination and her testimony regarding her interactions with the Walla Walla County Health Department nurses, but I do not find it persuasive enough to overcome the weight of her contemporaneous medical records. Although I found petitioner and her husband to be credible witnesses insofar as I do not question their sincerity and believe they sought to be truthful, I did not find their recollections sufficiently reliable to overcome the contradictory documentation.

At the time of the hearing, petitioner was testifying about events that happened between four to five years prior. In many instances petitioner was unable to recall certain details of her medical history and found it necessary during the course of her testimony to defer to her medical records regarding the details of her condition at the time, the date(s) of certain reports of symptoms, or the treatments she received.[14] (Tr. 23-24, 25, 47,68-69, 81, 98, 106, 109.) In particular, as noted above, petitioner could not recall why she completed her chiropractic intake form in the way that she did. (Tr. 23-24.) Additionally, petitioner was inconsistent in describing the overall course of her condition. Initially she described a period of improvement (Tr. 19, 92) before later indicating that the condition did not change over time (Tr. 35).

The fact that petitioner waited many months to seek treatment of her condition does not in itself factor significantly into my conclusion; nor does the fact that she resorted primarily to chiropractic rather than orthopedic care. Petitioner has credibly addressed her delay in seeking treatment of her shoulder pain, noting that she lacked insurance coverage and had difficulty affording proper care. (Tr. 20, 83-84.) However, this circumstance does not explain why, when she did eventually seek treatment, she would have initially reported the onset of her condition as falling in December of 2014 rather than directly linking the onset of her pain to her Tdap vaccination as she did in much later records.

Petitioner now describes a relatively vivid and unbroken recollection of shoulder pain originating at the time of her Tdap vaccination, "dramatically" changing her routine, and persisting since that time. (Tr. 19-20, 46-47.) She testified that she knew immediately that her injury was vaccine-caused. (Tr. 47.) However, even accounting for her lack of insurance coverage, that recollection is incongruent with her initial pattern of treatment and the notations in the contemporaneous records which are themselves clear and consistent, albeit sparse due to her limited treatment. Indeed, petitioner's January 23, 2015 chiropractic intake form specifically prompted her to indicate the cause of her pain and she wrote "nerve?" rather than relating her pain in any way to her prior Tdap vaccination. (Ex. 4, p. 21.) She also marked "none" when prompted to list "all significant trauma."[15] (*Id*.) Moreover, petitioner treated with her chiropractor three times over the course of three months from January to March of 2015 on the basis that her pain originated in December of 2014 for unknown reasons. Though I do not doubt the sincerity of her hindsight recollection, it is unlikely she would have done this if her understanding of vaccination-induced onset were as clear and strong as she now suggests.

[14] In one instance, quite candidly, petitioner said of her chiropractic record "[t]hat has to be correct because it's on the record here. I may not remember that anymore, but when I see it on the record, I am not going to disagree with the record." (Tr. 102.)

[15] Notably, however, petitioner also marked "none" on her later 2016 intake form in response to the same prompt despite having expressed in that form that her injury was caused by her Tdap vaccination. (Ex. 11, p. 27.)

b. Scope of Petitioner's Symptoms

An additional issue is presented by the record of this case in that, even if petitioner's shoulder pain was temporally related to her Tdap vaccination, there is not preponderant evidence that her "pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered" as required by the QAI for SIRVA. 42 C.F.R. §100.3(c)(10). Every time petitioner sought care for her condition, she was unwavering in describing her pain as extending to her neck as well as her shoulder and arm. (Ex. 3, pp. 1-5; Ex. 4, pp. 17, 19, 21, 26-27; Ex. 5, pp. 8-9.) Significantly, petitioner's records confirm that she continued to include reports of both neck pain and pain radiating down her arm to her hand even after she came to believe that she was suffering a SIRVA. (Ex. 3, pp. 1-5; Ex. 5, pp. 8-9.) Her subsequent affidavit also continues to describe pain in both the neck and radiating down her arm. (Ex. 6, pp. 2-3.) She also confirmed this during her testimony as well as testifying that she experienced numbness and tingling in her arm. (Tr. 23, 34, 86-87.)

Moreover, petitioner's chiropractor purported to find segmental dysfunction of the cervical vertebra which he opined "are capable of producing the complaints described by Ms. Demitor." (Ex. 4, p. 19.) Although the chiropractor ultimately concluded that orthopedic treatment was more appropriate and petitioner's shoulder complaints were "outside the realm of chiropractic," he did not retract his impression of segmental dysfunction. (*Id*. at 28.) Significant in that regard, petitioner did include neck pain in her report of symptoms to her orthopedist and, although the orthopedist diagnosed only left shoulder pain, biceps tendinitis, and subacromial tendinitis, nothing in his report rules out additional spine or neck concerns. (Ex. 3, pp. 1-5.) Notably, the orthopedist disclaimed any knowledge of SIRVAs and did not address the cause of petitioner's condition. (*Id*. at 4.)

V. Conclusion

The above findings of fact are incompatible with petitioner's claim of a Table SIRVA, which is the only claim that petitioner included in her petition. Moreover, I cannot find for petitioner "based on the claims of petitioner alone, unsubstantiated by medical records or by medical opinion," yet none of petitioner's treating physicians attributed her shoulder pain to her vaccination. 42. U.S.C. §300aa-13(a)(1). Accordingly, petitioner should move for dismissal of this case unless she has a reasonable basis to file an amended petition asserting a cause-in-fact claim that is supported by medical opinion and consistent with the above findings of fact.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master